



URGENT FIELD SAFETY NOTICE
Recall: RSP Glenoid Head Inserter 804-03-041

July 12, 2010

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Germany

Dear Mr. [REDACTED]

We would like to inform you of a product recall for the RSP Glenoid Head Inserter. Complaint data has shown a high number of complaint returns for the Glenoid Head Inserters due to fractures of the distal threaded tip. The fractures are thought to be a result of: (1) impaction loads, (2) bending loads, (3) a combination of impaction and bending loads. Although a bulletin updating the technique to instruct no impaction on this device was sent to the field, a number of these have still been damaged. Risks associated with this failure mode include surgical delay and/or the stainless steel tip of the inserter being left in the Glenoid Head preventing implantation of the glenoid retaining screw. In response to this we have designed a new Glenoid Head Inserter. The new design (804-03-051) incorporates the following changes: (1) impactor plate removed to reduce the ability for the surgeon to impact the inserter (2) material change of the stainless steel alloy from 17-4 (H900) to 465 (H950), which increases the yield and impact strength by approximately 30% (3) diameter of the tip shaft increased to resist bending forces.

Instructions:

1. Locate all RSP Glenoid Head Inserters.
2. Contact your International Customer Service Representative for an R-RPR (RMA) number.
3. Complete the Field Safety Notice Response page enclosed.
4. Return all RSP Glenoid Head Inserters, 804-03-041, under the assigned R-RPR number. The new inserters, 804-03-051, will be sent out on a Sales Order through Customer Service. You will receive credit for the Sales Order when you return the Glenoid Head Inserter(s) under the assigned R-RPR number.
5. Return the Field Safety Notice Response page to [REDACTED] at [REDACTED]@diosurgical.com or fax to +1-512-834-6313. All forms should be completed and returned by July 30, 2010. Completion of this form is mandatory for each agency.
6. If any of these devices have been further distributed/sold, identify those customers and inform them of this Field Safety Notice. A copy of this Field Safety Notice may be given to the consignee. Document this action on the Field Safety Notice Response. NOTE: This is not applicable to consignment agreements.

FDA and all relevant Competent Authorities have been advised of this Recall/Field Safety Notice.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call [REDACTED] International Customer Service, at +1 (512) 834-6275. You may also contact our EU Authorized Representative, MDSS GmbH, via email at info@mdss.com or via phone at +49 (0) 511 6262 8630.

Best regards,

[REDACTED]

[REDACTED]

Manager, Regulatory Affairs



Encore Medical, L.P.
9800 Metric Blvd

Austin, TX 78758-5445 USA



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Field Safety Notice Response

RSP Glenoid Head Inserter – Must be completed for each Agency by July 30, 2010

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the July 12, 2010 letter.
- I have checked my stock and have the following devices:

Part Number	Quantity our Records indicate in your inventory	Quantity Verified	R-RPR (RMA) number assigned
804-03-041	6		

- I have identified and notified any customers that were distributed/sold this product by (Not applicable to consignee agreements): _____
(specify date and method of notification)

Name: _____

Title: _____

Telephone Number: _____

Firm Name: _____

Address: _____

Please Fax or Email Completed Response Form to: _____

Fax: +1 (512) 834-6313

Email: _____@djosurgical.com

OR MAIL TO:

DJO Surgical

Attn: _____

9800 Metric Blvd.

Austin, TX 78758

Please Ship Product Return to:

DJO Surgical

9800 Metric Boulevard

Austin, TX 78758

Attn: RPR # _____